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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,674	08/19/2003	Suong-Hyu Hyon	1736-000001/REB	5762
27572 7590 10/28/2008 HARNESSE, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER BERMAN, SUSAN W	
			ART UNIT	PAPER NUMBER
			1796	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/643,674

Applicant(s)

HYON, SUONG-HYU

Examiner

/Susan W. Berman/

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-53,84-97,99-101,111-118 and 128-136 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-53,84-97,99-101,111-118 and 128-136 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/16/08</u> | 6) <input type="checkbox"/> Other: _____ |

Objection to the Application under 37 CFR 1.172(a)

The objection to this application under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. Applicant has filed, on November 0, 2007, the proper assents of the assignee in compliance with 37 CFR 1.172 and 3.73(b), as required in reply to the previous Office Action.

Oath/Declaration

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

The oath or declaration is defective because:

It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing.

Applicant has claimed priority to a Japanese application in the patent file that is not identified in the Reissue Declaration.

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414. The error set forth in the Declaration filed 08-19-2003 that embodiments focusing on preferred levels of irradiation, i.e. at least about 1 MR, were not specifically claimed is not relevant to the instant claims in this divisional application. The error or errors being corrected in this divisional reissue application must be specifically identified in the Declaration.

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In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 104, 109, 114, 130, 135, 136, 139, 144, 145 and 149-168 are rejected as being based upon a defective reissue Application Declaration under 35 U.S.C. 251. See 37 CFR 1.175.

The nature of the defects is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

See MPEP § 1414.01.

Response to Remarks

Applicant states that a new reissue oath/declaration will be provided prior to allowance of the present divisional application.

The rejection of claims 40-53, 84-97, 99-101, 111-118 and 128-136 under 35 U.S.C. 112, second paragraph, set forth in the previous office action is withdrawn.

Rejection under 35 U.S.C. 251: Applicants argue that the claims are not barred by the recapture rule because the broader aspects of the reissued claims do not relate to subject matter surrendered during prosecution. Applicant argues that the present claims are directed to a different invention than prosecuted in the issued parent. This argument is unpersuasive because issued claims 3-6 in US 6,168,626 are drawn to a method correspond to the method set forth in the instant claims. Applicant further argues that applicant's remarks and amendments in pursuit of the original claims are not relevant to the scope of the claims because the instant claims were

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restricted from the original claims as being drawn to a distinct and independent invention.

Applicant further argues that if the present claims are viewed as being the same invention as those issued they are materially narrowed in other aspects so as to avoid recapture. Applicant argues that the present amendments narrowing the recited heating to heating below the melting point to the melting point avoids the recapture bar because this aspect is also related to the rejections in the parent application. This argument is unpersuasive because this limitation was recited and prosecuted in the parent application.

In the instant case, reissue claims 40, 84, 111 and 128 are considered to be broadened in an aspect germane to surrendered subject matter in response to a prior art rejection and narrowed in another aspect unrelated to the rejection to claims in the issued parent and thus barred by the recapture rule. Claims 40, 84, 111 and 128 are broader by recitation of UHMWPE "block" rather than UHMWPE "molded block...compression plane", "subjecting said heated block to pressure" instead of "compressing the block in a direction perpendicular to a compression plane so as to deform the block", and omitting the requirement of a given "thickness range" after cooling.

Claims 40, 84, 111 and 128 are now narrowed by the recitation "heating...to a compression deformable temperature below the melting point of the UHMWPE". The narrowing of the compression deformable temperature recitation is not considered to be directed to an amendment and/or argument made to overcome a prior art rejection in the original prosecution and thus there is recapture of surrendered material. See MPEP 1412.02 [R-5] C. The Third Step 2(a) Issued claim 3 merely recites "heating...to a compression-deformable temperature". The issue "heating...to a compression-deformable temperature" compared with "heating to a

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compression-deformable temperature below the melting point' is not related to the surrendered material in the prosecution of the original application.

Prior art Rejections:

The rejections of claims under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sun et al (5,414,049) are moot since the claims are canceled.

Rejection under 35 U.S.C. 251

Claims 40-53, 84-101, 111-118 and 128-136 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

The following subject matter appears to be an attempt to recapture subject matter surrendered during prosecution of the parent application:

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The amendments cited below were made in parent application Serial No. 08/640,738, which issued as Patent 6,168,626.

In Amendment B filed 04-02-1997, the phrase "molded articles" was amended to set forth a **"molded articles having orientation of crystal planes"** in order to distinguish over Rosenzweig, US 5,030,487. The phrase "molded articles having orientation of crystal planes" was further amended to read **"molded articles having orientation of crystal planes in a direction parallel to a compression plane, wherein the molded article is crosslinked slightly"** in Amendment C filed 12/5/1997 in order to distinguish over cited Patent 4,655,769 to Zachariades.

The current recitation "block" in claims 40, 84, 111 and 128 is a broadening of the recitation of a "molded block" set forth in the original claims. The phrase "molded article" was changed to read **"molded block"** in Amendment F filed 02-25-1999 in order to distinguish over Patent 3,886,056 to Kitamaru et al. The current term "block" is broader in scope than the phrase "molded block" and broader in scope than the recitation **"molded block having been crosslinked slightly ... so as to have orientation of crystal planes in a direction parallel to the compression plane"** as set forth in claim 1 after Amendment F in Application No 10/640,738..

Applicant added the limitation **"having a molecular weight not less than 5 million"** to define the UHMWPE molded block in the step of slightly crosslinking an UHMWPE molded block by irradiating the block with a high energy ray. This limitation was added in Amendment H filed 05-04-2000 in order to distinguish over Kitamaru et al, but is missing from the instant claims.

The instant claims are broadened by failing to recite that the molded article is made by compression deforming the heated article **“by compressing the block in a direction perpendicular to a compression plane so as to deform the block”**. This limitation was added in Amendment D filed 09-03-1998 in order to resolve the rejection under 35 US 112, second paragraph, that the phrase “orientation of crystal planes in a direction parallel to a compression plane” discussed above was indefinite when the orientation of the compression plane is not defined.

The instant claims do not recite the limitation **“said block after cooling having a thickness range of 5 to 10 mm in a direction perpendicular to the compression plane”**. Amendment G filed 09-10-1999 introduced this limitation to distinguish the “molded block” recitation from the films and sheets disclosed by Kitamura et al.

Amendment G filed 09-10-1999 also introduced the limitation **“under pressure”** to the phrase “keeping the block in a deformed state under pressure” in order to distinguish over the process taught by Kitamura et al.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42, 44, 86, 88, 113, 115, 130 and 132 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 42, 44, 86, 88, 113, 115, 130 and 132 do not have antecedent basis in claim 40 or claim 84 or claim 111 or claim 128. The heating step

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(b) in claim 40 is limited to a temperature below the melting point of UHMWPE, while claims 42 and 44 recite heating to 80⁰C higher than the melting temperature.

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 42, 44, 86, 88, 113, 115, 130 and 132 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitamaru et al (3,886,056). Kitamaru et al disclose a process for irradiating polyethylene, including polyethylene preferably having a molecular weight from 2×10^5 to 1×10^6 and polyethylene having a molecular weight of 4×10^6 , with ionizing radiation to produce crosslinked polyethylene having a gel content of at least one weight percent (column 1, line 65, to column 2, line 50). Irradiation of polyethylene with dosages from 0.2 to 16 Mrads is taught in column 3, lines 1-10. A process comprising heating to produce a molten state, extending the polyethylene under increased pressure, and cooling the article while the extended dimension is maintained is taught in column 3, lines 13- 45. Irradiation followed by compression at 180⁰C followed by cooling and orientation of crystal planes in a direction parallel to the compression plane is disclosed in Examples 1-3.

Claims 40-53, 84-97, 100-101, 111-118, 128-134 and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zachariades (5,030,402) in view of Kitamaru et al (3866,056). Zachariades teaches compression deformation of oriented UHMWPE to obtain

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enhanced properties. Compression molding at between 80°C and the melting temperature of the polymer, preferably between 100°C and 130°C , and shaping into a final product is taught in column 3, lines 25-44. Zachariades also teaches maintaining pressure after cooling to ambient temperature to aid in retaining the attained chain orientation (column 4, lines 1-11). Zachariades further teaches that the molded UHMWPE can be thermally annealed after removal from the mold (column 6, lines 50-54). Zachariades discloses radiation crosslinking as a post-processing step (column 4, lines 11-18). Deformation of the UHMWPE perform to an acetabular liner is shown in Figures 4 and 5. The difference from the instantly claimed method is that Zachariades does not mention crosslinking UHMWPE by irradiation before compression deformation.

Kitamaru et al disclose a process for irradiating polyethylene, including polyethylene preferably having a molecular weight from 2×10^5 to 1×10^6 and polyethylene having a molecular weight of 4×10^6 , with ionizing radiation to produce crosslinked polyethylene having a gel content of at least one weight percent (column 1, line 65, to column 2, line 50). Irradiation of polyethylene with dosages from 0.2 to 16 Mrads is taught in column 3, lines 1-10. A process comprising heating to produce a molten state, extending the polyethylene under increased pressure, and cooling the article while the extended dimension is maintained is taught in column 3, lines 13- 45. Irradiation followed by compression at 180°C followed by cooling and orientation of crystal planes in a direction parallel to the compression plane is disclosed in Examples 1-3.

It would have been obvious to one skilled in the art at the time of the invention to irradiate UHMWPE, as taught by Kitamaru et al in an analogous method, to provide a slightly crosslinked irradiated UHMWPE perform as the starting UHMWPE to be used in the

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compression molding method steps for orienting and extending UHMWPE taught by Zachariades. Zachariades teaches that those skilled in the art to which the disclosed invention relates would recognize changes and different embodiments possible without departing from the spirit and scope of the invention. Zachariades provides further motivation by teaching that the UHMWPE can be radiation crosslinked after molding under pressure. Kitamaru et al provide motivation to employ irradiated UHMWPE by teaching that irradiation crosslinked UHMWPE can be deformed under pressure and will provide a high melting temperature and softening temperature polyethylene with improved transparency and excellent dimensional stability at high temperatures (column 1, lines 5-9, and column 2, lines 13-25). One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of obtaining both enhanced mechanical properties resulting from the disclosed compression deformation method taught by Zachariades and enhanced properties resulting from irradiation crosslinking before deformation of the crosslinked UHMWPE taught by Kitamaru et al. With respect to claims 49 and 50, It would have been obvious to one skilled in the art at the time of the invention to determine the thickness of UHMWPE product desired for a particular application and to prepare the block according to the combination of the teachings of Kitamaru et al and Zachariades as set forth above. Kitamaru et al do not teach any thickness limitations. Zachariades teaches treating polyethylene having thickness greater than the thickness set forth in the instant claims in the examples.

Claims 99 and 135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zachariades (5,030,402) in view of Kitamaru et al (3866,056), as applied to claims 40-53, 84-97,

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100-101, 111-118, 128-134 and 136 above, and further in view of Li et al (5,037,928). Neither Zachariades nor Kitamaru et al teaches cutting a block of UHMWPE to obtain a component for implant. Li et al disclose a process for manufacturing UHMWLPE shaped articles comprising heating and cooling in an inert gas atmosphere. Li et al teach heating UHMWLPE under pressure followed by cooling under pressure and cooling while releasing the pressure without allowing remelting, including forming an UHMWLPE article either before heating or after heating and cooling (column 2, line 43, to column 3, line 20 and column 5, lines 1-5). Li et al also teach that the disclosed process is particularly useful for manufacturing shaped articles from materials having cross-sectional dimensions of at least 1 inch by 1 inch and having temperature gradient problems during the cooling step and for producing articles at least 0.2 inch in thickness (column 3, lines 46-58). Example 5 discloses cutting and machining the treated UHMWPE bar.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-53, 84-97, 99-101, 111-118 and 128-136 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 104, 109, 114, 130, 135, 136, 139, 144, 145 and 149-168 of copending Application No. 10/643673. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method set forth in the instant claims includes the same steps set forth in the claims of A.N. 10/643673.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067.

The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
1/8/2008

/Susan W Berman/
Primary Examiner
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